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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/789,436	02/26/2004	William R. Patterson	355492-3150	5693

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EXAMINER	
ROGERS, JAMES WILLIAM	
ART UNIT	**PAPER NUMBER**
1618	
MAIL DATE	**DELIVERY MODE**
05/25/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/789,436	PATTERSON ET AL.	
	Examiner	Art Unit	
	James W. Rogers, Ph.D.	1618	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *21 February 2007*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-40* is/are pending in the application.

4a) Of the above claim(s) *23-29* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) *1-22 and 30-40* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *27 February 2004* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *12/27/2004*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Election/Restrictions

Applicant's election with traverse of Group I in the reply filed on 02/21/2007 is acknowledged. The traversal is on the ground(s) that a proper search of the methods recited in group II would necessitate a search of the compositions of group I and therefore there is no serious burden on the examiner to search all of the claims. This is not found persuasive because as stated in the previous office action dated 01/26/2007 the method may be used with various compositions depending upon the viscosity of the composition, thus a search for the method would not necessarily result in a search for the composition putting an undue burden on the examiner.

The requirement is still deemed proper and is therefore made FINAL.

The examiner notes applicants elected species, ethylene vinyl alcohol, dimethylsulfoxide and tantalum. Claims 23-29 are withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected invention, there being no allowable generic or linking claim. Applicant timely traversed the restriction (election) requirement in the reply filed on 02/21/2007.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1,10-11,20-21 and 22 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The term "sufficient" is claim 1 is a relative term, which renders the claim indefinite. The term "sufficient" is not defined by the claim, the specification does not provide a standard for ascertaining the requisite degree, and one of ordinary skill in the art would not be reasonably apprised of the scope of the invention. The term "sufficient" fails to specifically set forth the exact of rheological modifier necessary to impart a shear-thinning index to the composition.

Regarding claims 10-11,20-21 and 22 are indefinite because the recitation of ethylene vinyl alcohol is considered unclear by the examiner because it is generally understood by the skilled artisan that ethylene vinyl alcohol (EVOH) is a copolymer and is generally referred to as ethylene vinyl alcohol copolymer not just "ethylene vinyl alcohol", which may just refer to a monomer. The reason for this rejection is that it may not be clear to one of ordinary skill in the art that the recitation of EVOH is referring to a copolymer. The examiner suggests amending the claims to include the word "copolymer" after the recitation of "ethylene vinyl alcohol" throughout the claims.

Regarding claims 21 and 22 the claims are indefinite with respect to the weight % being claimed, for instance is the weight percent of the ethylene vinyl alcohol, tantalum and fumed silica the percent weight of each to the whole composition including solvent or just the weight percent of those components in relation to each other. Further clarification in the claims is required.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 1-16,18-23, 30-36,38-40 are rejected under 35 U.S.C. 102(e) as being anticipated by Porter et al. (US 2004/0156781 A1).

Porter teaches polymer-embolizing compositions for filling cavities of the body and kits comprising such compositions. See abstract. The composition comprises 3-12 % by weight of polymer (including EVOH), 20-55% contrast agent (including tantalum), about 1-12% rheological modifier (including fumed-silica), solvent (including DMSO) and other ingredients such as surfactants, the weight percents above are within the ratios and percents claimed by applicants. See [0062],[0067],[0074],[0079],[0091],[0096]. Regarding the limitations in the claims on the viscosity of the composition, since the compositions have the same ingredients and the same concentrations it is inherent that the same composition will have the same properties such as viscosity. Where the claimed and prior art products are identical or substantially identical in structure or composition, or are produced by identical or substantially identical processes, a prima facie case or either anticipation or obviousness has been established, Thus the claiming of a new use, new function or unknown property which is inherently present in the prior art does not necessarily make the claim patentable. In re Best, 562 F.2d 1252, 1254, 195 USPQ 430, 433 (CCPA 1977). Regarding the limitations on a kit containing the composition of claim 1, Porter teaches that the compositions may be delivered by

syringes and catheters especially microcatheters and guide wires which are capable of providing access to vessels as small as 1 mm in diameter. See [0022],[0023],[0049] and [0100]. Regarding the limitation in claims 34-35 and 40 that the kit also comprises a vascular prosthesis, Porter teaches that a microballoon (considered by the examiner to be a vascular prosthesis) may be employed in combination with the embolic composition to attenuate blood flow. The examiner did not give any patentable weight to the limitation of claim 38 that the kit included directions for use, since it is inherent that a composition intended to be injected into the body to form a solid mass such as an embolism would come with directions for its use.

Claims 1-4,8-9,12-15,30-33 and 36-39 are rejected under 35 U.S.C. 102(e) as being anticipated by Porter (US 2003/0194389 A1).

Porter teaches an occlusive composition suitable for creating a solid mass such as an embolism in a body cavity such as a lumen. See abstract and [0017]. The composition comprises a poly(2-cyanoacrylate), a visualization agent (including tantalum), a suitable carrier (including DMSO) and a rheological modifier (including fumed silica). See [0037],[0047],[0049]. The occlusive composition can be administered alone or in combination with another endoluminal device such as balloon catheters, stents, stent grafts and coils. See [0059]. A catheter or microcatheter could be used to deliver the composition. See [0057]. The examiner did not give any patentable weight to the limitation of claim 38 that the kit included directions for use, since it is inherent that a composition intended to be injected into the body to form a solid mass such as an embolism would come with directions for its use.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 1-22 and 30-40 are rejected under 35 U.S.C. 103(a) as being unpatentable over Greff et al. (WO 00/71170 A1) in view of Porter (US 2003/0039696 A1).

Greff discloses high viscosity embolizing compositions comprised of from about 2-50 weight % of a biocompatible polymers including biodegradable polymers such as PEG and non-biodegradable polymers (including EVOH) and combinations thereof, from about 10-40 weight percent of a biocompatible contrast agent (including tantalum) and a biocompatible solvent (including DMSO). See claims 1-5,9-12 and 15-37. The method to deliver the composition could also employ a blood flow attenuating device

such as an inflatable microballoon. A delivery method that was particularly preferred to deliver the embolic composition was via a small diameter catheter connected to a threaded syringe. See pag 13 lin 16-30.

Greff does not mention the use of a rheological agent such as fumed silica.

Porter discloses embolic compositions with non-cyantoacrylate rheology modifying agents. The rheological modifying agent can impart an apparent viscosity of between 25 cP and 2000cP. See [0014]. Among the rheological agents that could be selected is fumed-silica in amounts between about 0 to about 75 percent. See [0048] and [0052]. Any suitable device for administering a liquid composition such as a microcatheter could deliver the composition, the invention could also employ any method of using a variety of commercially available devices including catheters, catheter wires, catheter coils, stents and catheter balloons. See [0019]. The compositions could also employ surfactants. The advantages of the disclosed rheological modifying agents is that the agent can impart properties on the liquid compositions such as improved viscosity, improved cohesiveness, and improved suspension.

It would have been prime facie obvious to a person of ordinary skill in the art at the time the claimed invention was made to combine the art described in the documents above because Greff discloses embolic compositions comprising all of applicants claimed invention except for the use of rheological modifying agents while Porter disclosed that the use of rheological agents such as fused silica was already well known in the art at the time of the invention to be useful in compositions intended for

embolization. The motivation to combine the above documents would be to form an embolic composition as in Greff but with the rheological modifying agents of Porter, the agents would impart improved viscosity, cohesiveness, and suspension to the composition. One with skill in the art could modify the composition of Greff and add the rheological modifiers of Porter and have a reasonable expectation of success because both compositions are similar in that they pertain to the same field of endeavor, embolic compositions and their compositions comprise many of the same type of ingredients. Thus, the claimed invention, taken as a whole was *prima facie* obvious over the combined teachings of the prior art.

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 1-4,8-9 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 7-16 and 20 of copending Application No. 10/789,946. Claims 1-4,8-9 are generic to all that is recited in claims 7-16 and 20 of U.S. Application No. 10/789,946. That is, claims 7-16 and 20 of U.S. Application No. 10/789,946 falls entirely within the scope of claims 1-4,8-9 or in other words, claims 1-4,8-9 are anticipated by claims 7-16 and 20 of U.S. Application No. 10/789,946. Although the conflicting claims are not identical, they are not patentably distinct from each other because both claim a composition comprising a biocompatible polymer, solvent, contrast or visualizing agent and fumed silica as a rheological modifier.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Conclusion

No claims are allowed. Any inquiry concerning this communication or earlier communications from the examiner should be directed to James W. Rogers, Ph.D., Ph.D. whose telephone number is (571) 272-7838. The examiner can normally be reached on 8:30-5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Mike Hartley can be reached on (571) 272-0616. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for

published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

MICHAEL G. HARTLEY
SUPERVISORY PATENT EXAMINER